May 12, 2006

Mark Bradley, Associate Deputy Administrator
USDA-AMS-TMP-NOP
Room 4008-South Building
1400 Independence Avenue, SW
Washington, DC 20250-0020

Comments on: Docket TM-06-06-PR

Dear Mark,

I have been an organic inspector for 19 years, and was founding chair of the Independent Organic Inspectors Association. I was co-author of the Organic Trade Association's American Organic Standards, and recently completed a 5-year term on the USDA's National Organic Standards Board (NOSB). I currently work as the University of Minnesota's Coordinator for Organic Agriculture Outreach.

I would like to thank the USDA for posting this proposed rule to address the Court mandated regulatory changes of June 9, 2004, as well as those required due to Congressional action on Nov. 10, 2005, amending the Organic Foods Production Act (OFPA).

I am concerned, however, that the language in the proposed rule is not clear and does not resolve all of the issues addressed in the Court ruling and Congressional amendment. If implemented as proposed, the rule change is likely to cause inconsistent implementation of the USDA regulation for organic production and handling.

I am further concerned by the unprecedented 15-day comment period. A May 12, 2006, posting on the NOP website states, "The proposed changes as mandated by the Court have been well publicized for over a year, as the Court decision was published on January 26, 2005." While there has been much speculation about the impact of the January 26, 2005, Court ruling, the public has not been exposed to the current thinking of the USDA until the proposed rule was posted on April 25, 2005. Fifteen days is not sufficient time for most members of the public to provide informed comments.

I offer the following detailed comments on Docket TM-06-06-PR:

<u>Synthetic Substances</u>

The docket states that "USDA will <u>not</u> have to revise the NOP regulations" regarding the use of synthetic substances used during the processing of organic products.

Docket TM-06-06-PR, in the fourth paragraph of page 4, states, "On November 10, 2005, Congress amended the OFPA by permitting the addition of synthetic substances appearing on the National List for use in products labeled "organic.""

The quoted statement is not completely accurate. Congress amended OFPA to allow synthetic *ingredients* on the National List, not synthetic *substances*.

On November 10, 2005, Congress amended Section 2111 (7 U.S.C. 6510) of the OFPA, to read, "(a) IN GENERAL. - For a handling operation to be certified under this title, each person on such handling operation shall not, with respect to any agricultural product covered by this title -
(1) add any synthetic ingredient not appearing on the National List during the processing or any postharvest handling of the product;"

It is important to note that Congress did not amend Section 2105 (6504) of OFPA, which reads, "to be sold or labeled as an organically produced agricultural product under this title, an agricultural products shall - (1) have been produced and handled without the use of synthetic chemicals, except as otherwise provided in this title."

As amended, there is no allowance in OFPA for the use of synthetic substances during handling, except for the use of synthetic *ingredients* that are on the National List [7 U.S.C. 6510(a)(1)]. Other synthetic substances, unless classified as *ingredients* under the Act and regulation, remain prohibited during processing and handling.

This topic was addressed on page 3, paragraph 2, of the Consent Final Judgment and Order, June 9, 2005, which states, "With respect to Count 3, 7 C.F.R §§ 205.600(b) and 605(b) are contrary to the OFPA and exceed the Secretary's rulemaking authority to the extent that they permit the addition of synthetic ingredients and processing aids in handling and processing of products which contain a minimum of 95% organic content and which are eligible to bear the USDA seal."

In order to allow the continued use of synthetic substances, including processing aids, adjuvants, indirect food additives, and food contact substances, and to protect the USDA from future legal action, USDA must clarify through rulemaking and guidance that all substances used in or on processed organic products, which have direct contact with organic processed products, are categorized as “ingredients” under regulations implementing the OFPA. All such ingredients must be subject to the National List process.

The definition of “ingredient” should be revised to be consistent with references to ingredients and substances used during the processing of organic products found at §205.105, §205.270(b), §205.301(b), and §205.605.

In addition, the Department still has a policy statement entitled, "*Synthetic Substances Subject to Review and Recommendation by the National Organic Standards Board When Such Substances are Used as Ingredients in Processed Food Products"* posted on the NOP website which specifically exempts an entire class of FDA-listed "Food Contact Substances" from the National List process and NOSB review. [Go to www.cfsan.fda.gov/%7Edms/opa-fcn.html to see the list of Food Contact Substances]

The NOP's Food Contact Substance policy statement is in direct conflict with the OFPA and the Court's Consent Final Judgment and Order.

In its court filings, the USDA stated that the current Food Contact Substance policy is not final, "was posted for discussion," and "is part of an ongoing deliberation about how the Act and Rule operate." [Brief of Appellee at 23-24, n. 11, Harvey v. Veneman, 396 F.3d 28 (1st Cir. 2005) (No. 04-1379).]

Recommended Actions

1) The USDA should withdraw the Policy Statement of December 12, 2002, entitled, "*Synthetic Substances Subject to Review and Recommendation by the National Organic Standards Board When Such Substances are Used as Ingredients in Processed Food Products."*

2) The USDA should issue a Policy Statement affirming that all substances used in or on processed organic products, which have direct contact with processed organic products, are considered ingredients under the OFPA and its implementing regulations. As such, all substances used in or on processed organic products are subject to National List procedures and must be reviewed by the National Organic Standards Board.

3) The USDA should conduct rulemaking to amend the definition of "ingredient" to assure that all substances used in or on processed organic products are considered ingredients under the OFPA. The definition of "ingredient" should be amended to read:

"§205.2 Terms defined
Ingredient.
Any substance which has direct contact with processed products used in or on the preparation of an organic agricultural product ~~that is still present in the final commercial product as consumed~~."

Criteria for Review of Synthetic Ingredients

As mentioned above, the Consent Final Judgment and Order, June 9, 2005, states, "With respect to Count 3, 7 C.F.R §§ 205.600(b) and 605(b) are contrary

to the OFPA and exceed the Secretary's rulemaking authority…"

The court found the § 205.600(b) criteria for the evaluation of synthetic ingredients and processing aids to be contrary to OFPA. The Congressional amendment did not restore the criteria.

Further, the criteria in § 205.600(b) specifically apply only to "any synthetic substance used as a *processing aid or adjuvant*." (italics added) The Final Rule contains no criteria for the evaluation of synthetic *ingredients*.

In order for the NOSB to evaluate petitioned synthetic ingredients and for USDA to place them on the National List, the criteria in § 205.600(b) must be reinstated and revised during the rulemaking process. The criteria must be amended to apply to all synthetic ingredients, rather than to synthetic processing aids and adjuvants.

Recommended Actions

1) Rules need to be issued to reinstate criteria for the evaluation for all substances petitioned for use in or on processed organic products.

2) The criteria in §205.600(b) should be re-written to read:
"(b) In addition to the criteria set forth in the Act, any synthetic substance used ~~as a~~ in or on a processed organic product ~~processing aid or adjuvant~~ will be evaluated against the following criteria:…"

Origin of Livestock

I support changes to §205.236(a)(2) to allow the use of "crops and forage from land included in the organic system plan of a dairy farm that is in the third year of organic management," as stated in the Congressional amendment to OFPA.

It should be noted, however, that the OFPA amendment and the new proposed rule change allow for the feeding of "crops and forages" from land in its third year of organic management, not just the "grazing of pastures," as repeatedly stated in Docket TM-06-06-PR's explanatory text (71 FR 24823).

As indicated, I have been an organic inspector for 19 years, and work with numerous organic certifying agents on implementation of their quality systems. In order to implement the new provision, and to verify that crops and forages fed to dairy animals for one year prior to production of organic milk are from land that is its third year of organic management and included in the operation's organic system plan, there will need to be inspection of the operation's crops and forages during the second year of organic management. Without inspection by a representative of an accredited certifying agent, there will be no way to verify compliance with new regulation.

According to the definition of “organic system plan” in §205.2, an OSP must be agreed to by the producer or handler and the certifying agent. In effect, an OSP does not exist until agreed to by a certifying agent. To implement the new provision, certifying agents will need to approve a dairy operation’s OSP prior to the feeding of crops and forages from land under its third year of organic management. Since the “third year feed” will have new regulatory status as allowed feed for dairy animals, compliance with organic standards will need to be verified prior to the feed being consumed by dairy animals for one year.

I suggest new requirements be added to §205.403 to authorize on-site inspections of applicant dairy operations to verify compliance with §205.236(a)(2).

I am further concerned that the language, as proposed, may inadvertently permit the use of crops and forage produced during the first two years of transition, since land that is not in third year transition, as well as stored crops and forage from previous harvests, may be “included in the organic system plan."

I suggest a punctuation change to indicate that crops and forage must come from land that is in the third year of transition to certified organic production.

Recommended Action

1) §205.403(b) should be amended by adding a new section §205.403(b)(3) to read:

“3) An on-site inspection of a dairy operation must be conducted prior to the beginning of the third year of organic management in order to verify that crops and forages, fed to dairy animals for one year prior to sale of organic milk and milk products, are certified organic or are from land that in its third year of organic management and are included in the operation’s organic system plan.”

2) Commas should be inserted in § 205.236(a)(2), as indicated below, to clarify that only crops and forages from land in its third year of transition to certified organic production may be fed to dairy animals during the 12-month period prior to production of organic milk and milk products.

§ 205.236 Origin of livestock. (a)

> “2) *Dairy animals* - conversion of herds. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic, Except, That, crops and forage from land, included in the organic system plan of a dairy farm, that is in the third year of organic management may be

consumed by the dairy animals of the farm during the 12-month period immediately prior to the sale of organic milk and milk products."

Origin of Livestock – Replacement Animals

While I appreciate retention of the clause in §205.236(a)(2)(i) that requires organic management from last third of gestation, I am concerned that it will continue the "two-track" certification system now in place for organic dairy operations.

In its May 12, 2006, web posting, USDA acknowledges that a two-track system exists, in stating, "USDA will initiate an advanced notice of proposed rulemaking to obtain input on how to address the concerns of interested parties in the organic community with respect to the two-track system for converting dairy replacement animals."

There is no need for an "advanced notice of proposed rulemaking" on this issue. The issue needs to be resolved in the Final Rule issued in response to this Proposed Rule, since it was presented in the explanatory text and Q & A issued by USDA on April 25, 2006, and since one of the purposes of the OFPA is "to assure consumers that organically produced products meet a consistent standard." [7 U.S.C. §6501(2)]

The text of the proposed rule raises new questions. It appears that the proposed regulation presents two ways that a dairy operation may be certified for the production of organic milk:

1. Organic management for one year, or
2. Via the exception, feed rations may include crops from land in the third year of transition.

Once the animal is converted through one of the two methods, it is not clear who is subject to the provision under proposed §205.236(a)(2)(i):

1. All certified dairy operations?
2. Only those operations that transition via the exception?
3. Only those operations that transition an "entire distinct herd"?

The explanation given in the USDA's April 25, 2006, Q and A posting states that the subparagraph applies to producers who convert "an entire distinct herd." The Q and A implies that a producer who does not convert "an entire distinct herd" does not have to abide by the requirement.

The phrase "an entire, distinct herd," as used in proposed §205.236(a)(2)(i), is not defined, and, with the removal of language previously in §205.236(a)(2), is out of context. "Herds" are not certified under the NOP – "operations" are certified, as described in the definitions of "certification or certified" and "certified operation" in §205.2.

The Congressional amendment did not use the term “entire, distinct herd,” and instead referred to a “dairy farm” and “dairy animals.” The regulation elsewhere describes certification of “operations,” not “herds” (§205.100, .237 and elsewhere). The term “entire, distinct herd” needs to be changed in the Final Rule.

It is consistent with the language adopted by Congress, the OFPA, the preamble to the Final Rule, the NOSB recommendation of May 2003, and the existing regulation to change “entire distinct herd” to “operation” to clarify that all operations must manage their young stock organically, no matter how the operation chose to become certified.

The rule must also be changed to require organic management of all replacement animals, both those purchased and those born on the farm, from the last third of gestation.

The preamble to the original Final Rule indicates that all dairy animals are to be managed organically from last third of gestation, once an operation has converted to organic production.

On October 20, 2002, the NOSB unanimously recommended that the regulation be interpreted to require that all dairy replacement animals be managed organically from the last third of gestation. The recommendation was supported by comments submitted by the Organic Trade Association, certifying agents, dairy farmers, and other members of the public.

After being told by NOP staff that rule change would be needed to correct the “two-track” certification system for dairy operations, on May 14, 2003, the NOSB unanimously voted in favor of a recommended rule change that would require organic management of replacement dairy animals for all certified organic dairy farms.

The requirement for organic management from last third of gestation is supported by and consistent with other sections of the regulation, including:

> §205.236(b)(1), which states, "Livestock or edible livestock products that are removed from an organic operation and subsequently managed on a nonorganic operation may be not sold, labeled, or represented as organically produced."
>
> And §205.238(c), which states, "The producer of an organic livestock operation must not: (1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.603, or any substance that contains a nonsynthetic substance

prohibited in § 205.604."

As the NOP stated in their 3/10/05 response to the NOSB regarding the rescinded directives, "the use of antibiotics and other prohibited substances is not allowed for organically produced livestock or their edible products once a producer is certified organic."

The lack of a requirement for organic management of all replacement animals will harm the market for organic heifers, and diminish demand for organic feed. It may allow young stock to be managed non-organically on a certified organic farm as part of a split operation. This will create continuing record keeping burdens and make verification of appropriate management extremely difficult. It will also decrease the supply of organic slaughter animals from dairy culls, and make tracking these animals more complex.

It is also potentially harmful to consumer demand since it allows for continuous importation of non-organic replacement animals, which may have been treated with antibiotics, hormones and non-organic feed. This issue is incorrectly represented on page 15 of Docket TM-06-06-PR. (FR 24823).

Dairy farms do continually replace a certain percentage of their animals each year. Without a consistent requirement for animals to be managed organically from the last third of gestation, a substantial percentage of the animals producing milk on organic dairy farms could have been fed substances prohibited in organic production, including genetically engineered feeds, blood, animal fat and other slaughter by-products allowed by FDA, and treated with prohibited medications for the first year of their lives.

The allowance of such practices is contrary to consumer expectations as described in marketing studies presented at the recent USDA sponsored Organic Dairy Symposium.[1]

Recommended Actions

1) §205.236(a)(2)(i) should be replaced by a new §205.236(a)(3), which reads:

> (3) *Dairy animals* - replacement stock. Once an operation has been certified for organic dairy production, all dairy animals, including all young stock whether subsequently born on or brought onto the operation, shall be under organic management from the last third of gestation.

[1] http://www.ams.usda.gov/nop/PublicComments/DairyPastureSymposium/MaryEllenMolyneux.pdf, http://www.ams.usda.gov/nop/PublicComments/DairyPastureSymposium/MargaretWittenbergPresentation

2) The current §205.236(a)(3) Breeder stock. should be re-numbered as §205.236(a)(4) Breeder stock.

Commercial Availability

The NOP did not propose language to implement the expedited petition allowance in the OFPA amendment. If USDA intends to exercise the authority granted under Congressional amendment, rulemaking must be conducted to establish the conditions and criteria for “emergency procedures” under which the Secretary shall determine agricultural products to be “Commercially Unavailable.” Such rulemaking must include a minimum 60-day comment period.

The continued inclusion of "made with organic ingredients" in both the title and the text of the proposed rule for §205.606 is a technical error. Nonorganic agricultural ingredients used in "MWO" products do not have to be listed on §205.606. They must be produced without GMOs, irradiation, and sewage sludge. Otherwise, so long as they comprise less than 30% of the product, they can be nonorganic, and do not have to appear on §205.606.

While this topic was not addressed in the Harvey lawsuit or the Congressional amendment, the text of the rule should be corrected during the rulemaking process.

Recommended Actions

1) Engage in rulemaking prior to establishment of “expedited petition” procedures to add nonorganic agricultural substances to the National List.

2) Remove references to “made with organic” products from the title and text of §205.606 to read:

“§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic ~~or made with organic ingredients~~.

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic” ~~or “made with organic (specified ingredients or food group(s)),”~~ only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.”

Phase In

The Proposed Rule in Docket TM-06-06-PR reads as if it is effective immediately. It should, consistent with the Court judgment, officially state in a Federal Register notice, rather than in a Q and A, that products produced in compliance with the

prior regulation may continue to be produced and sold until June 9, 2007.

Conclusion

I appreciate the opportunity to once again submit comments to the USDA. While I have found the time to draft and submit comments, I am concerned that many stakeholders were likely disenfranchised by the extremely short 15-day comment period.

Respectfully,

Jim Riddle
31762 Wiscoy Ridge Road
Winona, MN 55987
Ph/fax: 507-454-8310
riddl003@umn.edu